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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,095	02/08/2001	Jean-Louis Gueret	20982-13	1674

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/779,095	GUERET, JEAN-LOUIS	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-30 and 35-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-30 and 35-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's appeal brief filed 08/28/2006.

Claims 2-4, 31-34 have been canceled.

Claims 1, 5-30, 35-65 are pending and included in the prosecution.

The finality of the Office action mailed 03/28/2006 is hereby withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Claim 9 is directed to moisture absorbing compounds including "freeze-dried substances". The specification gives no guidance to one of ordinary skill in the art regarding "freeze-dried substances"

that fulfill the requirement as moisture absorbing compounds. The disclosure of the broad expression "freeze-dried substances" without partial or complete description of any freeze-dried substances does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The recitation of "freeze-dried substances" without any description of these substances and their correlation to the moisture absorbing compounds does not meet the written description requirement as one of ordinary skill in the art could not recognize or understand the what are the freeze dried materials that acts as moisture absorbing compounds. Claims employing broad terms at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of freeze-dried substances and applicants claimed "freeze-dried substances" represents only an invitation to experiment regarding possible means.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Vas-Cathy Inc. v Mahurkar, 19 USPQ 2d 1111. The invention is, for purpose of the "written description" inquiry, what ever is now claimed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11, 14, 21-23, 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 11, the expressions "wetting agents", "healing agents", "freshener", "vascular protectors", "liporegulator", "immunomodulators", and "skin conditions" do not set forth the metes and bounds of the claims. Recourse to the specification does not define the expressions.

Regarding claim 11, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite by raising a question or doubt introduced by a subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art. In the present instance, wide ranges are "anti-inflammatory agents" and "keratolytic agents" and the narrow range is "salicylic acid". Further, wide ranges are "softener", "skin conditions" and "moisturizer" and the narrow range is "glycerin". Further, wide ranges are "vascular protector", "nourishing agents" and "healing agents" and the narrow ranges are "vitamin A", "vitamin C" and "vitamin F". Further, wide ranges are "antioxidant" and "free radical scavengers" and the narrow ranges are "vitamin C" and "vitamin A".

Claim 11 further recites active agents that overlap in scope and renders the claim confusing, such as anti-aging agent and anti-wrinkle agent, and such as antioxidant and free radical scavengers.

Regarding claim 14, the recitation of "vinyl", which is a chemical group, as an adhesive does not set forth the metes and bounds of the claim. Recourse to the specification disclosed adhesives comprise vinyl.

Additionally, claim 14 is confusing as it recites "permanent adhesive comprises PVA and PVP", while on page 8, lines 22-23 of the present specification applicant disclosed PVA and PVP as revisable adhesives.

Claims 21-23 recite the limitation "support layers". There is insufficient antecedent basis for this limitation in the claim or in claim 1.

Regarding claims 36-41, the claims recite the expressions: "additional active agent configured to swell", "additional active agent soluble in the solvent", "compounds configures to swell". Recourse to the specification does not define the expressions.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,491,928 ('928).

The present claims 1, 54-56 are drawn to article comprising two non-adhesive layers, at least one of these layers is permeable to a solvent, and an adhesive layer

disposed between the two non-adhesive layers and comprises adhesive and active agent that can be delivered upon wetting of the article. Claim 27 is directed to conventional method of making the article that comprises the steps of coating the composition comprising the adhesive on the first non-adhesive layer, and then assembling the second non-adhesive layer.

US '928 teaches an article comprising first substrate and second substrate and a therapeutic composition disposed in between the two substrates (abstract; figure 3). The first substrate is perforated and made of permeable materials to enable passage of water (col.3, lines 50-66). The second substrate is can be apertures (col.9, lines 35-40). The therapeutic composition comprises active agent including the agents recited by claim 11 including conditioning agents, anti-acne, anti-wrinkles, anti-inflammatory, etc. (col. 25, lines 25-35). The substrates layers are made of non-woven material and can be permeable to water, as required by claims 15 and 16, or impermeable, as required by claim 18 (col.3, lines 64-67; col.4, lines 13-16; col.5, lines 23-25). The two non-adhesive substrates can have different texture, as required by claim 17 (col.3, lines 39-46). The active agent is released from the article when the article is wetted with water and contacted the hair or skin as required by the generic claims, and claims 5, 6, 47-49, 65 (col. 44, lines 13-31). The therapeutic agent comprised within composition comprising adhesive material (col. 31, lines 21-25). The therapeutic composition comprises cellulose or starches that are claimed by applicant as moisture absorbing compounds in claims 7 and 9 (col.36, lines 9-11; col. 37, lines 1-2). The reference also teaches gelling agents that also read on moisture absorbing agents and it is present in

an amount of 0.1 to 100% that encompasses the amounts claimed in claims 8 and 42 (col.36, lines 18-25). The gelling agents are capable to form a hydrogel and absorb water, and that reads on the limitations of claims 36-41. The reference teaches a method of making the article comprises the steps of adding the therapeutic composition to the first substrate then placing the second substrate on the first substrate as required by claim 27 (col.43, lines 65-67; col.4, lines 1-2). The therapeutic composition comprises polyamides claimed by applicants as inert materials in claim 10 (col.43, line 59). The reference teaches that the different active agents can be enclosed separate from one another (col.19, lines 60-65).

The set forth teaching of the reference meet the requirements of generic claims 1, 27, 54-56, and the dependent claims included in the rejection, except for the limitation that the two non-adhesive substrates are bonded permanently by the middle layer. It is notices that the adhesive used by the reference in the middle layer comprises acrylic polymer and polyurethane that are claimed by applicant as permanent adhesive in claim 14 (col.32, lines 40-43; col.37, lines col.39, lines 16-17). Hence, the middle layer disclosed by the reference that comprises adhesive including acrylic acid polymer or polyurethane polymers is expected to be able to permanently bond to the first and second non-adhesive substrates, absence of claiming amounts of the adhesive in the middle layer.

7. Claims 19-26, 28-30, 35, 45, 46, 53, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '928 in view of US 5,350,581 ('581).

The teachings of US '928 are discussed above.

US '928 suggested delivery of more than one active agent, and suggested to keep the different active ingredient separate.

However, US '928 does not teach more than one superimposed layers containing adhesive or pile of the article as claimed in claims 19-26, 28-30, 35, 45, 46, 53, and 58.

US '581 teaches multilayered transdermal therapeutic system assembled from superimposed monolithic unites to obtain the finished device (abstract). The device comprises more than one therapeutic agent contained in different adhesive matrices to deliver mixture of therapeutic agents (col.5, lines 30-55). The multilayered device has improved reliability and is produced by manipulable steps (col.2, lines 33-38). Example of drugs to be delivered by the device anti-inflammatory drugs, ant-histaminic drugs, and vasodilators (col.5, lines 58-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises adhesive and therapeutic agent wherein more than one active agents can be enclosed separate from one another in the article as disclosed by US '928, and provide the different active agent in more than one superimposed adhesive layers as disclosed by US '581, motivated by the teaching of US '581 that multilayered device has improved reliability and is produced by manipulable steps, and deliver mixture of beneficial therapeutic agents, with reasonable expectation of having article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises multiple

layers comprises adhesive and different therapeutic agent wherein more than one active agents can be delivered from improved reliable device.

8. Claim 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '928 in view of US 6,338,839 ('839).

The teachings of US '928 are discussed above.

US '928 teaches polyamide in the therapeutic composition.

However, the US '928 does not teach the polyamide in the powder form.

US '839 teaches topical cosmetic composition that has transfer resistance from the skin to the surfaces it comes in contact with (abstract; col.2, lines 17-20, 30-35). The composition comprises Orgasol which is polyamide powder (col.5, lines 4, 49-58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises therapeutic composition containing active agent and polyamide, as disclosed by US '928, and replace polyamide with polyamide powder as disclosed by US '839, motivated by the teaching of US '839 that composition comprising this powder has transfer resistance of the active agent from the skin to the surfaces it comes in contact with, with reasonable expectation of having an article comprising two outer layers and middle layer comprising active agent and polyamide powder wherein the active agent has transfer resistance on application to skin.

9. Claims 12, 13, 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '928 in view of JP 04108710 ('710).

The teachings of US '928 are discussed above, however US '928 does not teach magnetizable particles in the therapeutic composition.

JP '710 teaches cosmetic in adhesive matrix comprising magnetizable particles that are capable of promoting of blood flow to the skin without causing inflammation to the skin (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises adhesive and therapeutic agent as disclosed by US '928, and add magnetizable particles to the active agent containing layer as disclosed by JP '710, motivated by the teaching of JP '710 that the magnetizable particles are capable of promoting the blood flow to the skin without causing its inflammation, with reasonable expectation of having an article comprising two outer layers and middle adhesive layer comprising magnetizable particles that promotes the blood flow to the skin without causing its inflammation.

Response to Arguments

9. Applicant's arguments with respect to claims 1, 5-30, 35-64 have been considered but are moot in view of the new ground(s) of rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Examiner
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